

Contents

Volume 23, 1989

Volume 23, Number 1

1989

CONTENTS

- | | | |
|---|----|--|
| Alick J. Munro | 1 | Developing Procedure at Clinical Investigation Units |
| David A. Carlin
Peter Palmer | 5 | Problems, Pitfalls, and Solutions to the Development of an International Clinical Database |
| Paolo E. Lucchelli
Francesco Gianese | 11 | Planning a Clinical Research Program for Global Use |
| Dorle Messerer
Joerg Hasford | 15 | Monitoring Multicenter Trials and its Impact on Trial Results |
| Bruce P. Greenberg
Chialing C. Yen
Richard C. Accomando | 21 | Tracking of Clinical Data for an International Environment |
| Klaus Stern
Juergen Lilienthal
Wilhelm Sauermann
Reinhard Zentgraf | 25 | Requirements on an Integrated DBMS for Data From Clinical Trials |
| Gian Marco Leali
Patrizia Pugnetti | 37 | A Protocol-Independent Database for Clinical Studies |
| Richard A. Boulding | 55 | Problems of Global Clinical Data Management |
| Roland Blomer | 65 | Practical Relevance of Relational Database Properties for Clinical Database Management |
| Christian Benichou
Gaby Danan | 71 | Lack of Definitions of Adverse Drug Reactions |
| Erika F. Nissman
Domenic G. Iezzoni | 75 | Report on a WHO ART-COSTART Translation Project |
| Donna K. Jackson
Susan Pfasecki
Frank A. Adornato | 81 | Regulatory Perspective of Worldwide Marketing Authorization Applications |

David M. Cocchetto	87	Issues Regarding Compassionate Treatment With Investigational New Drugs
Jay H. Bauman Robert J. Fuentes	95	Drug Information at Glaxo Inc
Gérard B. Bailly Marc Pierredon Richard Rondel Lucien Steru Elie Szapiro	105	Phase IV and Europe
Steven R. Miola	117	Preparing an Individual Clinical Study Report
Mary Ellen Kitler	123	The Elderly in Clinical Trials: Regulatory Concerns
Eric van der Putten Hilary R. Franklin	139	Quality Control in Phase I-III Cancer Clinical Trials
Klaus Abt Iain T. R. Cockburn Albert Guelich P. Krupp	143	Evaluation of Adverse Drug Reactions by Means of the Life Table Method
Roger P. Nelson	151	Organization of Information Departments in the US Pharmaceutical Industry
Bams Abila	165	Efforts to Monitor Adverse Drug Reactions in Africa: A Case Study of Nigeria
	I	Software Survey Section

CONTENTS

**Computer-based Systems for Storage,
Reporting, and Analysis of Worldwide Postmarketing Drug Safety Data**

Harry A. Guess	169	Worldwide Drug Safety Information Processing—What's Ahead?
Linda Hostelley	171	Reporting and Tracking Spontaneous Adverse Experience Reports via a Computer Database
Fred Schneiweiss	179	Capture and Analysis of Spontaneous Adverse Event Data at A. H. Robins

- Win M. Castle 183 The ICI Approach: Possible Adverse Reaction Information System
- John C. C. Talbot 189 Database Management and Reporting Systems—Foreign-based Companies: The Glaxo Approach
- Hugh H. Tilson 197 *Discussion Panel: Database Management and Reporting Systems of Foreign-based Companies*
- Lorely J. E. Maskell 203 Wellcome Group Computer-based System for Worldwide Adverse Drug Reaction Report Management
- Judith M. Sills 211 World Health Organization Adverse Reaction Terminology Dictionary
- Terry L. Gillum 217 The Merck Regulatory Dictionary: A Pragmatically Developed Drug Effects Vocabulary
- Charles Anello 221 Electronic Submission of Periodic Reports
- James C. Mannion 225 Turning Computer Reports Into Labeling Changes
- Harry A. Guess 231 *Discussion Panel: What Can Validly be Done with Spontaneous Adverse Drug Experience Reports?*

Additional Articles

- H. C. Faulkner III 245 Database Design and Management in a Pharmacokinetic Department
R. H. Farmen
- L. Edward Kirk 257 Retrovir® (zidovudine): A Unique Drug Information Challenge
G. Edward Collins
Michael C. Joseph
Deborah Katz
- Steven J. Blumenthal 267 Discovery of the New Drug Therapies Based on the Study of Adverse Reactions
- Martha M. Rumore 273 Comparison of Drug Information Practice in Hospitals and Industry
Jack M. Rosenberg
- Alan M. Daly 285 A Microcomputer-based Data Acquisition and Reporting System for Clinical Pathology Data from Animal Drug Toxicology Studies
Ronald A. Martin
Edward J. McGuire
Carlo J. Di Fonzo
- Frances E. Nolan 297 Computerization of the Pathology Application Area
- David W. Gaylor 303 Estimation of Cancer Risk

- Marie A. Abate** 309 Information Sources Utilized by Private Practice
Arthur I. Jacknowitz and University Physicians
James M. Shumway
- Jacqueline Anne Sayers** 321 An Alternative Approach to Clinical Research
Paul Blake Associate Training
- Ingrida S. Sketris** 327 Developing a Quality Assurance Program for Drug
Anne Bishop Information Requests Answered by Staff
Emily Somers Pharmacists
G. Ross Baker
- Bams Abila** 335 Drug Discovery: Need to Explore African
 Phytoresources
- Elisabeth Poy** 339 Quality Assurance of Clinical Trials and Good
John Donahue Clinical Practices in France
- I Software Survey Section:
Entrypoint 90

 Volume 23, Number 3

1989

CONTENTS

- Roger W. Croswell** 345 Guest Editor's Note
- 347 Preface
- Roger W. Croswell** 349 Welcome and Introduction
Alastair G. Ramsay
- Roger W. Croswell** 353 Session 1: A Brief Overview of the Similarities and
 Differences between the US and EEC Chemical and
 Pharmaceutical Requirements for Clinical Trials and
 for the Marketing Authorization/NDA
- Anthony S. Anginoli** 355 Comparative Requirements for Initiating Clinical
 Trials (Including IND and CTC)
- Roger W. Croswell** 365 Questions and Answers: Session 1
- Kevin McKenna** 371 An Overview and Comparison of the US and EEC
 Chemical and Pharmaceutical Requirements for the
 Marketing Authorization/New Drug Application
- Roger W. Croswell** 379 Initiation of Working Groups

- Charles S. Kumkumian** 391 Session 2: Detailed Review of US and EEC Documentation Requirements for the Active Constituent
- Charles S. Kumkumian** 393 Requirements for the Active Constituent and Available Guidelines
- George R. Wellman** 395 The Active Constituent: US and EEC Requirements for Documenting the Method of Preparation, Control of Starting Materials and Intermediates, Control of the Final Bulk Product, and Batch Analyses (Including Those from Toxicology and Clinical Studies) to Support Proposed Impurity Limits
- Charles S. Kumkumian** 405 The Reference Standard: US and EEC Requirements for Documenting the Proof of Structure and Physical/Chemical Properties
- M. O'Brien** 411 US and EEC Requirements for Documenting the Stability of the Active Constituent
- Richard Margerison** 417 Recommendations for a Truly International Registration Dossier
- Charles S. Kumkumian** 421 Questions and Answers: Session 2
- Anthony C. Cartwright** 427 Session 3: A Detailed Review of US and EEC Documentation Requirements for the Final Dosage Form and Available Guidelines
- Klaus Salm** 429 The Dosage Form: US and EEC Requirements for Documenting the Method of Preparation and Control of Clinical Trials' Supplies and the Final Dosage Form Proposed for Marketing
Arnold Urdang
- Anthony C. Cartwright** 439 Comments
- G. R. Dukes** 441 The Dosage Form – US and EEC Requirements for Documenting Its Stability for Clinical Trials and Marketing
C. H. Bibart
- Anthony C. Cartwright** 449 Questions and Answers: The Dosage Form Stability
- J. Michael Morris** 453 US and EEC Requirements for Documenting Process and Methods Validation
- Karen Hoerlyk** 463 The Final Dosage Form: Effectively Dealing with Differences in Local and National Requirements
- Anthony C. Cartwright** 469 Questions and Answers: Session 3

Yuan-yuan H. Chiu	477	Session 4: Review and Discussion of Special Chemical and Pharmaceutical Requirements in the US for Biotechnology Products
Huib Van de Donk	483	Effectively Dealing with the Special Chemical and Pharmaceutical Considerations in the US and EEC for Biotechnology Products—Part 1A
Birgit Priefke	495	Effectively Dealing with the Special Chemical and Pharmaceutical Considerations in the US and EEC for Biotechnology Products—Part 1B
Alan Dinner John Fose	501	Effectively Dealing with the Special Chemical and Pharmaceutical Considerations in the US and EEC for Biotechnology Products—Part 2
Yuan-yuan H. Chiu	511	Questions and Answers: Session 4
Alastair G. Ramsay	515	Working Group 1: The Active Constituent—A Model International Registration Dossier
Kevin McKenna	529	Working Group 2: The Final Dosage Form—A Model International Registration Dossier
Kevin McKenna	539	Report of the Working Group on "The Finished Dosage Form"
Anthony C. Cartwright Charles S. Kumkumian Klaus Salm	543	Summary and Closing Remarks: Where to from Here?
Harvey Gurien Gary M. Klee	545	Core Requirements for International Registration of Drugs (New Chemical Entities): Manufacturing and Controls
	561	Workshop Contributors
	I	Software Survey Section: <i>INQUIRE/Text</i>

CONTENTS

**Promotional and Marketing Activities:
Preapproval, Time of Approval, Postapproval**

Wayne L. Pines	563	Foreword
Wayne L. Pines	565	A Perspective on Pharmaceutical Marketing

Lloyd Millstein	571	Preparing to Market a New Product
Gail R. Safian	577	Marketing Issues in the Preapproval Stage
Robert C. deGroof	581	Research for a Marketing Plan
William W. Vodra	585	How the FDA Regulates Drug Promotion and Medical Education Before Drug Approval
Kenneth R. Feather	597	Preapproval Promotion: FDA's View
John Chervokas	601	Medical Advertising in the 1990s
Thomas D'Alonzo	605	Co-marketing as an Innovative Marketing Technique
Joseph A. Romano	609	Overview of Current Marketing Issues
Tom Webber	615	The Launch of Xanax
Wendy Borow	619	New Ideas in Medical Education: Medical TV
Kenneth P. Berkowitz	623	Perspectives on Promotional Regulations
David G. Adams	625	FDA Regulation of Promotion of Drugs: A Legal Primer
Louis A. Morris David Banks	635	Current FDA Policies on Drug Promotion
James H. Stewart	641	Marketing to Managed Care Institutions
Wayne I. Roe	647	Reimbursement Planning for New Pharmaceuticals: Strategic Challenges in the 1990s
Sheila Raviv	653	Working with and through Third-party Groups
Charles L. Fry	657	Innovations in Drug Marketing
Additional Articles		
Judi Weissinger	663	Considerations in the Development of Stereoisomeric Drugs: FDA Viewpoint
Wesley Mark Todd	669	Phase I Trials: Past, Present, and Future
R. Vander Stichele M. G. Bogaert	673	Patient Package Inserts: The Belgian Experience with a Mandatory Program
Albert Weissman	679	On the Designation of Race in Clinical Pharmacology Reports

Robert W. Ashworth	687	IND Requirements for Biotechnology Products
George S. Hughes, Jr	693	Challenges in the Design of Phase I and Early Phase II Studies
Beverly M. De Vries	699	Recruitment of Volunteers for Phase I and Phase II Drug Development Studies
George S. Hughes, Jr		
Steven F. Francom		
J. S. Mohrland	705	Use of Microcomputers to Monitor an Offshore Phase I Clinical Trial
W. J. Bryan		
	709	Letters to the Editor
	I	Software Survey Section
	V	Volume 23 Contents and Author Index

